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November 3, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comments on docket 98N-0673

To Whom It May Concern:

Listed below are our comments regarding the documents *Revisions to the Requirements Applicable to Blood, Blood Components and Source Plasma; Direct Final Rule* and *Revisions to the Requirements Applicable to Blood, Blood Components and Source Plasma; Companion Document to Direct Final Rule.* Thank you for your consideration of our comments in formulating the final rules.

1. 21 CFR 640.2
   This section states that the blood container shall not be entered prior to issue for any purpose except for blood collection. This statement precludes the ability to enter the unit for special processing, such as filtering to make a unit leukoreduced, washing to make a unit IgA deficient, splitting a unit for transfusion to a neonate, as well as pooling of platelets and cryoprecipitate. In some of these instances, it is possible to use a sterile connection device, but not for all. We are sure that the FDA does not intend to preclude all these activities.

2. 21 CFR 640.4(g) and 640.15
   References to pilot tubes and pilot samples have been replaced with the words *samples* or *segments.* § 640.4(g) deals with "Samples for laboratory tests" and § 640.15 deals with "Samples for testing". We find the wording used in these two sections confusing. § 640.15(b) addresses the need to mark or identify segments prior to filling so as to relate them to the donor of that unit, but no such requirement in stated for the samples in § 640.4(g)(2), which is where we believe it belongs. The samples collected at the time of filling the original container are those used for communicable disease testing and ABO and Rh determination. Such samples are the most critical to be marked for traceability back to the donor. Because of the change in terminology, § 640.15(b) now reads "Before they are filled, all segments shall be marked or identified so as to relate them to the donor of that unit of red cells." Currently sample tubes are marked prior to filling so that they are traceable to the donor by placing a facility assigned unique identifier (i.e. unit identification number) on the sample tubes. However, no such process takes place for segments. Currently all manufacturers of blood bags identify the bag tubing, which eventually is heat sealed and becomes the segments, with a unique identifier. This unique identifier is NOT the manufacturers' bag lot number. By introduction of the wording change for § 640.15(b), there is now an implication that any facility preparing products must track this manufacturers' unique tubing identifier, in addition to the already tracked manufacturers' bag lot number and the unique identifier assigned by the blood collection facility (i.e. unit identification number). Alternatively, the collection facility could identify the segments by attaching their unique identification number to the tubing, but it would require attachment to each segment. Because segments are used for testing predominantly by the transfusion service, not the

98N-0673 C3

donor collection center, identifying segments prior to filling has no added value unless they are marked in a manner that is meaningful to the transfusion service. Does the FDA mean to imply that such tracking or segment identification must occur and exclude the more critical sample identification that must occur at collection of the unit?

3. 21 CFR 640.56(c)
FDA proposes to reword § 640.56(c) to state, "The quality control test for potency may be performed by a clinical laboratory which meets the standards of the Clinical Laboratory Improvement Act of 1988 (CLIA) (42 U.S.C. 263a) and is qualified to perform potency tests for antihemophilic factor..." How does a laboratory become "qualified" to perform potency tests for antihemophilic factor? FDA should indicate exactly the definition of such qualification.

4. 21 CFR 640.23(a)
FDA proposes to reword § 640.23(a) to state, "Blood from which plasma is separated for the preparation of Platelets or Platelets, Pheresis shall be tested as prescribed in §§ 610.40 and 610.45 of this chapter and § 640.5(a), (b), and (c). Results of tests performed in accordance with § 640.5 (b) and (c) for Platelets, Pheresis products shall be valid for a period not to exceed 3 months." We believe that introducing an extended period for testing on only a limited number of tests will introduce the potential for error, in that other tests, which should have been performed, will inadvertently be omitted. Furthermore, the extension to 3 months is inconsistent with the American Association of Blood Banks requirements for testing. The AABB allows all testing to be repeated at 30-day intervals, but only if the donor is dedicated to a particular patient. In docket No. 98N-0581, the FDA is requesting comment on whether to exempt from testing for evidence of infection due to communicable disease agents listed in § 610.40(a) each donation of dedicated apheresis donors. To minimize error, it would be much better to use the same time interval for all "exempted" testing. We encourage the FDA to harmonize their requirements with those of the AABB regarding time frame, that is, none of the testing in 610.40, 610.45 or 640.5 need be repeated for any cytapheresis donor except every 30 days. However, we prefer that the qualifier for dedicated donors not be a part of the FDA requirement, since it is relatively easy to keep track of whether the donor was tested or not, but not so easy to keep track of whether the testing was done under a dedicated donor process or not.

Sincerely,

S Breanndan Moore

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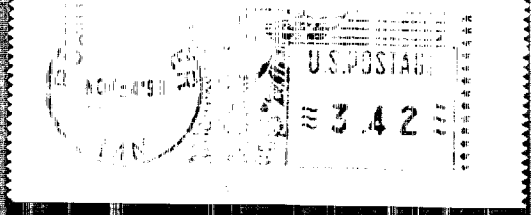
Chair, Division of Transfusion Medicine

cc: Mary Foss
Tania Motschman



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From: Tania Motschman

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